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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,477	03/21/2005	Steve Brian Gendreau	EX03-051C-US	2298

20306 7590 08/31/2006

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EXAMINER	
BRISTOL, LYNN ANNE	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/523,477	GENDREAU ET AL.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-24 are all the pending claims for this application and subject to lack of unity restriction under 35 U.S.C. 121 and 372.

2. Claims 1 and 20 are directed to methods of using AXIN pathway modulatory agents where the substrate is a MAX polypeptide or nucleotide. Because the MAX substrate of a polypeptide or a nucleotide is distinct and separate as discussed below, the method claims have been restricted into groups on the basis of the substrate compositions.

Lack of Unity Restriction

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature that appears to link claims 1-24 are AXIN pathway modulatory agents that bind MAX polypeptides or nucleotides. Applicants are reminded that because the claims recite "comprising" language, the claims are given the broadest reasonable interpretation in light of the specification. Thus, any AXIN binding protein or agent affecting an Axin nucleic acid could be encompassed as claimed and as taught, for example, by Nishida et al. (J. Biol. Chem. 276(42):39060-39066 (2001); cited in the IDS of March 24, 2005) (sumo-1/smt-specific isopeptidase); Kadoya et al. (J. Biol. Chem. 275(47):37030-37037 (2000); cited

in the IDS of March 24, 2005 (Axam or Axin associating molecule); or Kadoya et al. (Mol Cell Biol. 2002 Jun;22(11):3803-3819)(desumoylation enzyme). Therefore the technical feature recited in claims 1-24 is not a contribution over the prior art. Accordingly the groups set forth below are not so linked as to form a single general concept under PCT Rule 13.1.

4. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, Claims 1-7, 11,12 and 16-19, drawn to a method for identifying a candidate agent for modulating the AXIN pathway comprising contacting a MAX polypeptide with the test agent.

Group 2, Claims 1-3, 6, 8-12 and 16-19, drawn to a method for identifying a test agent for modulating the AXIN pathway comprising contacting a MAX nucleotide with the test agent.

Group 3, Claims 13-15 and 20-22, drawn to a method of modulating the AXIN pathway in a cell comprising contacting a MAX polypeptide with a candidate modulator.

Group 4, Claims 20-22, drawn to a method of modulating the AXIN pathway in a cell comprising contacting a MAX nucleotide with a candidate modulator.

Group 5, Claims 23 and 24, drawn to a method of diagnosing a disease in a patient comprising contacting a sample with a probe for MAX expression.

5. The inventions listed as Groups 1-5 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

corresponding special technical features for the following reasons: As set forth above in view of the teachings from the reference documents, the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature shared by Groups 1-5 is not special.

The inventions are distinct and separate for the following reasons:

6. The methods of Groups 1-5 differ in the method objectives, method steps and parameters, intended populations and in the reagents used.

The method inventions of Groups 1 and 2 for identifying modulating agents, Groups 3 and 4 for modulating an Axin pathway in a cell, and Group 5 for diagnosing a disease in a patient sample with a MAX probe are distinct and separate because:

a) the method steps and method objectives are different: Groups 1 and 2 requires the steps of identifying modulating agents requires comparing a test agent condition versus a reference condition in order to identify a test agent that up- or down-regulates Axin activity vis-à-vis interaction with MAX protein or nucleic acid; Groups 3 and 4 requires the steps of restoring Axin-deficiency in a cell with an agent binding to MAX protein or nucleic acid; and Group 5 requires obtaining a biological sample from a patient in order to diagnose a disease with a probe for MAX expression.

b) the modulatory agents encompassed by Groups 1-5 are different: Groups 1 and 3 requires test agents that bind to the MAX protein and Groups 2 and 4 requires test agents that bind to MAX nucleic acids.

Because the method inventions are distinct and separate for the foregoing reasons restriction as indicated is appropriate.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of Species

8. If any one of Groups 1 or 2 is elected, the species (assay system) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie 1) apoptosis assay

Specie 2) cell proliferation

Specie 3) angiogenesis

Specie 4) hypoxic induction assay

Species 1-4 represent distinct and separate assays comprising different steps, biological readouts for method effects and method objectives. The species are not obvious variants or overlapping.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 generic as to Species 1-4.

9. If any one of Groups 1 or 3 is elected, then species (candidate modulator) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie 1) antibody

Specie 2) small molecule

The species represent distinct and separate compounds and non-obvious variants, because an antibody has a unique amino acid sequence and a small molecule has a unique chemical structure.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1 and 20 are generic as to Species 1 and 2.

10. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

11. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

12. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER